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The Hidden Dangers of Falsified and Substandard Medicines

Developing Countries Are Most Affected by the Illegal Trade

Judith Vorrath and Maike Voss

When talking about health risks in developing countries, many people think of events such as the Ebola virus epidemic in 2014 and 2015 in West Africa. The effects of trade in falsified and substandard medicines are far less known. Developing countries are particularly affected since they are easy targets for the illegal trade due to insufficient regulations and controls as well as limited access to health care. The health and (socio-)economic consequences are severe. Moreover, criminal networks make large profits, usually without having to fear any significant punishment. The German government can push for a stronger focus on the issue at the World Health Assembly in May 2019. Germany's bilateral engagement should, above all, support developing countries in making drug supply chains safer.

According to World Health Organization (WHO) data from 2017, about one in ten medicines in middle- and low-income countries is substandard or falsified. Based on the WHO definition, this means that drugs are deliberately faked, are not approved for the destination market, or do not meet quality standards despite authorisation. Few cases have generated media responses like the one concerning the illegal production in the Middle East of the amphetamine-type stimulant Captagon, which was allegedly distributed systematically to fighters of the "Islamic State". In most cases, the illegal business in pharmaceutical products attracts little attention.

Between 2013 and 2017, 42 per cent of all reports sent to the WHO Global Surveil-

lance and Monitoring System on substandard and falsified medicines worldwide came from Africa. Overall, flaws are most frequently reported for antibiotics and drugs used to treat malaria. This also puts at risk the achievement of the Sustainable Development Goal for good health and well-being (Goal 3), which concerns access to universal health care services and safe, effective, quality, and affordable essential medicines (Target 3.8). However, the damage caused by substandard and falsified medicines is much more multifaceted.



Risks and Implications of Falsified and Substandard Drugs

Substandard and falsified antimalarials cause an estimated 116,000 deaths annually in sub-Saharan Africa, according to a WHO study. The underlying report's focus is mostly on medicines that have been fraudulently manufactured. These medical products deliberately endanger the health of patients when containing no or false active ingredients. In particular, substandard pharmaceuticals contribute to antimicrobial resistance.

People with limited access to health care services or who are dependent on medical treatment for a longer period of time are most affected.

In addition, there is financial damage for patients, but also for companies and the economy as a whole. In the case of anti-malarials in sub-Saharan Africa, the estimated annual cost to patients and health care is \$38.5 million due to additional after-care. In turn, substitute ingredients added to falsified medicines can pose additional health risks that require further and longer treatment. Scandals about fake drugs and ineffective and harmful therapies also undermine trust in the health care system. Those affected may use its services less often or only very late.

Apart from the effects on public health, criminal networks generate high profits through the illicit trade in pharmaceuticals. However, this trade often has no visible consequences on public safety. Thus, the dangers associated with it tend to be hidden and are often underestimated.

Illicit Trade and Pharmaceutical Crime

Substandard medical products are often the result of a lack of care during their manufacture. Yet, they might enter legal supply chains — running across different countries or even continents — at various points. Sometimes such drugs are also traded illegally. In contrast, falsified medicines are produced deliberately — sometimes clan-

destinely, but also by officially registered pharmaceutical companies that basically serve as fronts. The most commonly named countries of origin for these fraudulent drugs are China and India, where active ingredients, but also components like the packaging or the labelling are faked to deceive consumers. To ensure that the products do not attract attention in simple laboratory tests, active ingredients are sometimes added, but rarely in adequate amounts. Ultimately, falsified medicines reach the end-user via illegal distribution channels or they find their way into legal supply chains.

According to an Interpol report from 2014, traditional organised crime is involved in this trade to a limited extent. As far as it is known, informal international networks with structures similar to those of genuine enterprises tend to dominate the illegal business. However, apart from a small steering group, their members usually do not know each other. The value of the trade in counterfeit medicines, which is increasingly taking place online, is estimated at \$70 to \$200 billion annually.

Pharmaceutical crime varies greatly from region to region. Developing countries in Africa and South-East Asia are of particular interest as target markets for fraudulent medicines. Weak health systems, combined with miscalculations concerning demand of health services, offer favourable conditions there. Although the spending on pharmaceuticals is lower overall in developing countries, demand is rising while regulatory instruments are weak. Moreover, large sections of the population still have no access to adequate and high-quality health care.

At the same time, illegal distribution via online pharmacies is less important than in Europe, for example. This is because market access for predominantly imported drugs is poorly regulated in many developing countries. Various medicines are also sold on the street and in barely controlled shops. In addition, drugs can easily be smuggled, especially in cargo containers. Such trafficked pharmaceutical products are also misused, like the painkiller Tramadol in West Africa.

In this case, illicitly traded medicine used as a substitute for heroin leads to further health problems.

As part of the 10-day operation ACIM (Action against Counterfeit and Illicit Medicines), which was carried out by 16 African customs administrations in 2016, pharmaceuticals worth around €52 million were confiscated. But such internationally supported operations remain selective. There is a fundamental lack of technologies to guarantee product safety and enable traceability. In practice, countries are particularly short of laboratories for quality control, and effective prosecution is a major challenge.

Moreover, the scope of international cooperation is limited. Among the members of the Permanent Forum on International Pharmaceutical Crime as an operational platform, for example, the only developing country is South Africa. As the risk of being exposed and punished is rather low, the profits of criminal networks remain high. In addition to prosecuting criminal networks, there is a need for approaches focussing on markets and supply chains that offer developing countries appropriate solutions.

Making Supply Chains Safer

So far, there is no global regulatory framework addressing the illicit trade in medical products. The Council of Europe's Medici-crime Convention is a binding international instrument that can also be ratified by non-member states. However, only three African countries have made use of this option so far. This makes it all the more important to support regional and national measures that enable developing countries to keep low-quality and harmful medicines out of their markets. In line with the WHO monitoring system ("prevent, detect, respond"), however, these measures should not only be reactive but focus on the whole supply chain, up to the end-consumer.

Firstly, imports are of particular relevance. Developing countries generally import most medicines or receive them from

aid organisations. However, in places where domestic production increases, measures need to be extended to ensure the quality of the medicines produced. If production is poorly controlled — while at the same time there is better monitoring in countries such as China — this can result in increased fraudulent activities.

Secondly, regulation has to be more targeted. The number of officially approved entry points for pharmaceutical products can be reduced, all while ensuring that products are distributed nation-wide to the end-consumer. Together with stronger networking between health actors, pharmaceutical regulatory authorities, customs, and law enforcement, this can help to significantly improve surveillance, as has been the case in Nigeria since 2003. Moreover, in many countries, there are no specific laws for pharmaceutical crimes; rather, they treat the relevant cases as simple fraud or the infringement of intellectual property rights. Legislative proposals should distinguish between deliberate fakes and infringements of intellectual property rights in cases where the composition and effects of the drugs are not objectionable. Otherwise, the authorities will be overloaded with prosecuting less serious offences.

Thirdly, when controlling the access, the main difficulties lie in the quick identification of low-quality and falsified medicines and appropriate follow-up processes, such as their complete removal from distribution channels. Warnings on potentially affected drugs have to be circulated among the authorities and, if necessary, they have to be recalled. Ideally, after medicines have been seized, there should be investigations to identify those responsible for the illegal trade.

Fourthly, effective approaches are needed to control the quality of medicines when distributed and sold to consumers or patients. In European Union countries, manufacturers, distributors, and pharmacies check the authenticity of prescription medicines by means of security features on the packaging and consolidate data on distribution channels in a European drug verifica-

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tion system. In the medium term, there should be procedures without gaps along the supply chain in developing countries, and these should be coordinated regionally, as far as possible. However, as long as there are no comprehensive “track and trace” systems, local organisations can also monitor medicines with inexpensive rapid tests – a practice that can be accompanied by research projects. Countries such as Ghana are working with apps that can be used to check and report the codes on packaging. Here, however, the burden of monitoring basically lies with the consumer. Raising the awareness of the population is, therefore, essential in this context.

Starting Points for Multilateral and Bilateral Engagement

At the World Health Assembly in May, there are several starting points for Germany to address the issue at the interface of health and security. The international pharmaceutical industry could be obliged to develop a common monitoring system for falsified and substandard medicines based on the European model. This would allow for detecting anomalies at an early stage – both inside and outside companies – especially if these reports were also sent to the WHO Global Surveillance and Monitoring System. This way, the information would not harm an individual company, but rather increase the security level of the whole supply chain. The activities of the working groups under the WHO mechanism on substandard and falsified medical products are also important. Germany could step up its commitment in this field. However, representatives from only 53 of the 194 WHO member states took part in the last meeting of the mechanism, in November 2018, which shows that many countries are not actively involved. Thus,

it would be important to promote exchanges among developing countries beyond individual regional conferences. Last but not least, bilateral support remains essential. Two fundamental aspects need to be taken into account here.

First, technical assistance in the health and security sectors must systematically address the integrity of the actors involved. From the procurement of drugs to the prosecution of serious forms of pharmaceutical crime, susceptibility to corruption must be reduced. It is not all about know-how, skills, and equipment; control mechanisms and checks and balances within and between authorities are also important. The procurement of safe medicines, especially within the framework of development co-operation, is also supported through certifications and training courses offered by the WHO, among others.

Second, access to safe, effective, and affordable medicines must be improved overall. Otherwise, there will continue to be a high demand for cheap – but often unreliable – pharmaceuticals that are sold informally. Programmes financed by Germany to strengthen health systems should include the monitoring and control of supply chains as part of universal health coverage.

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